K093977

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c)

Submitted by:
Chestnut Medical Technologies, Inc.
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APR 22 2010

Contact Person: Daniel Cher, M.D.

Date summary prepared: December 11, 2009

Trade Name: Alligator™-HD Retrieval Device, ARD-HD

Common Name: Endovascular snare device

Classification Name: Catheter, Percutaneous (21 CFR 870.1250, Product Code DQY)

Device Description:

The Alligator™-HD Retrieval Device (ARD-HD) is a retriever with grasping jaws attached to the tip of a flexible wire. The device is designed to be used in conjunction with an off-the-shelf 0.21 in. (0.51mm) ID (inner diameter) microcatheter. The grasping jaws and the distal end of the ARD-HD device are made of radio opaque material facilitating fluoroscopic visualization. The ARD-HD is for single use only.

Indications for Use:

The Alligator™-HD Retrieval Device is intended for use in the peripheral, neuro and cardiovasculature for foreign body retrieval.

Predicate Device: Alligator™ Retrieval Device; 510k # K043580, Boston Scientific, Target In-Time Retrieval Device; 510k# K014109, Microvena Corp. Amplatz Microsnare, 510k# K970668

Comparison to Predicate Devices to Support Substantial Equivalence Determination:

The information presented in the 510k shows that the Alligator™-HD Retrieval Device, ARD-HD is substantially equivalent to predicate endovascular snare devices in regards to the following aspects:

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Design:	The subject (Alligator™-HD Retrieval Device, ARD-HD) and predicate device (Alligator™ Retrieval Device; 510k # K043580) are substantially equivalent with respect to design and technological characteristics. Both are made of similar materials and fabricated using the same manufacturing procedures.
Function:	The subject and predicate devices are substantially equivalent with respect to functional characteristics. The subjective device will be provided with shorter lengths and one size larger size jaw for the cardiovascular indication.
Manufacturing:	The subject and predicate devices are similar with respect to technological manufacturing processes.
Materials:	The subject and predicate devices are composed of identical material composition, all of which have an extensive clinical history of safe use in medical devices. Although the differences in construction and materials are incidental, the ARD-HD was tested for biocompatibility.
Indications:	The subject (Alligator™-HD Retrieval Device, ARD-HD) and predicate device (Alligator™ Retrieval Device, ARD) are substantially equivalent with respect to the indication. The predicate ARD is intended for use in the peripheral and neurovasculature for foreign body retrieval. The subject ARD-HD is intended for use in the peripheral, neuro and cardiovasculature for foreign body retrieval. The cardiovasculature indication was granted to the predicate devices: Boston Scientific, Target In-Time Retrieval Device; 510k# K014109Microvena Corp. Amplatz Microsnare, 510k# K970668
Packaging:	The subject and predicate devices utilize identical packaging configurations.
Sterilization:	The subject and predicate devices are both sterilized utilizing an Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.*
Labeling:	Both the subject and predicate devices have similar labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 22 2010

Chestnut Medical Technologies, Inc.
c/o Dr. Daniel Cher
VP of Clinical and Regulatory Affairs
173 Jefferson Drive
Menlo Park, CA 94025

Re: K093977
Trade/Device Name: Alligator™-HD Retrieval Device, ARD-HD
Common Name: Endovascular snare device, Catheter, Percutaneous
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: April 5, 2010
Received: April 7, 2010

Dear Dr. Cher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be assigned K093977

Device Name: Alligator™-HD Retrieval Device

Indications for Use:

The Alligator™-HD Retrieval Device is intended for use in the peripheral, neuro and cardiovasculature for foreign body retrieval.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
Number K093977